

Application Serial No. 09/720,762

Attorney Docket No. 114174.00014

Amendment and Response to Office Action Dated May 1, 2006

**REMARKS/ARGUMENTS**

Claims 1, 3 and 6-17 are now pending, a total of 14 claims. Claims 1 and 9 are independent. Independent claims 1 and 9 are amended. Dependent claim 2, 4 and 5 were previously canceled. Dependent claims 3, 6-8 and 10-17 are unchanged.

**I. Independent Claims 1 and 9**

The specification was objected to under 35 U.S.C. § 132(a) as introducing new matter into the disclosure based on the phrase "wherein the restriction that is not laminated" recited in claims 1 and 9.

In addition, claims 1, 3, 6-17 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement based on the phrase "wherein the restriction that is not laminated" recited in claims 1 and 9.

Claims 1, 3, 6-17 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Trull et al. (U.S. 6,080,136), and Ito (U.S. 5,063, 025).

Independent claim 1, as amended, recites as follows:

1. A gasket for a pre-filled syringe, the syringe comprising a barrel into which liquid is charged, wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin.

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The Office Action concedes that Trull et al. has no disclosure that a plunger surface may be coated. The Office Action argues that Ito, in column 5, lines 1-7, teaches that a syringe gasket is commonly coated with a thermoplastic resin such as polyethylene or polypropylene (TEFLON). The Office Action then concludes without any supporting evidence that it would have been obvious to modify the Trull et al. gasket by using the polyethylene or polypropylene coating of Ito.

To establish prima facie obviousness, all claim limitations must be taught or suggested by the prior art. MPEP § 2143.03. Each step in an obviousness inquiry must be supported by "substantial evidence." MPEP § 2142-2144.09. The deficiencies of a reference cannot be remedied by the Examiner's general conclusions about what is "basic knowledge" or "common sense" to one of ordinary skill in the art. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001). The Office Action directly concedes that Trull et al. does not teach or suggest any gasket coating. The Office Action does not allege that the Ito reference teaches applying a coating only to the outer surface of the plunger that contacts the inner surface of the syringe barrel.

There is no teaching or suggestion in Ito to apply a coating to "the peripheral side surface that contacts the inner surface of the syringe barrel," as recited in claim 1. Ito does not teach or suggest selectively applying a coating to plunger surfaces in any manner. Thus, pursuant to 37 C.F.R. § 1.104(d)(2), Applicant requests a reference or an affidavit to support any alleged "motivation to modify" Trull et al. or Ito to apply a coating to a surface of a tapered plunger that contacts the inner surface of the syringe barrel.

Nothing in the cited references -- Trull et al. or Ito, individually or in combination -- teaches or suggests a syringe gasket "wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein a

Application Serial No. 09/720,762

Attorney Docket No. 114174.00014

Amendment and Response to Office Action Dated May 1, 2006

periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a tapered slant, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin." Thus, independent claim 1 is not anticipated, taught, or suggested by the art of record.

Independent claim 9 similarly recites a syringe gasket "wherein a peripheral side surface of the gasket that contacts an inner surface of the syringe barrel is provided with a restriction, and wherein only the peripheral side surface that contacts the inner surface of the syringe barrel is laminated with polyethylene fluoride resin, and wherein a periphery of a bottom surface of the gasket that is not for contact with the liquid is formed into a first tapered slant, and a second tapered slant is formed between the peripheral side surface of the gasket that contacts the inner surface of the syringe barrel and the restriction." For at least the reasons discussed above, claim 9 is also patentable over the combination of Trull et al. and Ito.

Independent claims 1 and 9 meet the requirements of 35 U.S.C. § 112. No new matter has been introduced. See, e.g., original claim 3.

## II. Dependent Claims

The dependent claims are patentable with independent claims 1 and 9, as discussed above. In addition, the dependent claims recite additional features that further distinguish the cited references.

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Attorney Docket No. 114174.00014

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In view of the foregoing, Applicant respectfully submits that the claims are in condition for allowance. Applicant therefore requests that the application be passed to issuance. The Examiner may telephone Applicant's undersigned counsel at the number below concerning prosecution of this application.

Also enclosed is a Petition for Extension of Time for one (1) month.

WILLKIE FARR & GALLAGHER, LLP

Dated: May 1, 2006

By: \_\_\_\_\_

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